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MAR 26 2002

Ms. Lisa Haskell
Manager, Labeling
Solgar Vitamin & Herb
500 Willow Tree Road
Leonia, New Jersey 07506

Dear Ms. Haskell:

This is in response to your letter of October 30, 2002 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). In your letter, you notified us about a claim you intend to use for your dietary supplement **Daily Harvest Cholesterol Support**.

The product **Daily Harvest Cholesterol Support** uses the claim "Cholesterol Support." In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1018), FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. We stated, however, that because "many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease," in order to avoid implying that the product prevents or treats heart disease, a cholesterol maintenance claim would have to clarify that the product is only for maintenance of cholesterol levels that are already within the normal range. The claim for your product, including the name "Daily Harvest Cholesterol Support", which itself is a claim that the product is intended to effect blood cholesterol levels, contains no such clarification, however. Therefore, FDA considers the claim "Cholesterol Support" and the name of the product itself to be implied claims to prevent coronary heart disease by preventing the development of elevated cholesterol levels or reducing elevated cholesterol.

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product, including the name of the product, suggests that it is intended to treat, prevent, or mitigate a disease. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

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Please contact us if we may be of further assistance.

Sincerely,



John B. Foret

Director

Division of Compliance and Enforcement

Office of Nutritional Products, Labeling

and Dietary Supplements

Center for Food Safety

and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, Seattle District Office, Office of Compliance, HFR-PA340



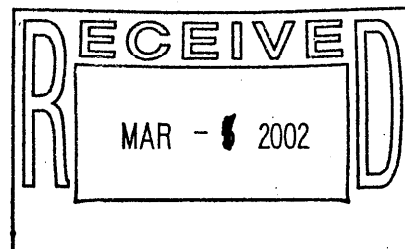
SOLGAR VITAMIN AND HERB
WORLD HEADQUARTERS

500 WILLOW TREE ROAD, LEONIA, NJ 07605 USA
PHONE 201-944-2311 FAX 201-944-7351



October 30, 2001

Office of Nutritional Products
Labeling and Dietary Supplements (HFS-810)
FOOD AND DRUG ADMINISTRATION
200 C Street, S.W.
Washington, D.C. 20204



RE: Notification for Statement on Dietary Supplement

Dear Sir/Madam:

In compliance with the Dietary Supplement Health and Education Act of 1994, **Daily Harvest Natural Vitamins** hereby makes its official notification under Section 101.93 that it has included a statement listed in Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act on its label. Accordingly, enclosed please find two (2) copies of this Notification. The following information is being provided:

The dietary supplement is being distributed by:

DAILY HARVEST, LLC.
163 Madison Avenue, Floor 2
Morristown, NJ 07960 USA

The name of the dietary supplement, the name of the dietary ingredients contained in the product which are the subject of this Notice, the text of the statement and structure/function claims are listed on the attached sheet.

I hereby certify that the information presented and contained in this notice is complete and accurate, and my files contain substantiation that the statements made are truthful and not misleading.

Thank you for your time and attention to this matter. If you have any questions, please do not hesitate to contact the undersigned.

Very truly yours,
DAILY HARVEST NATURAL VITAMINS

Lisa Haskell, Manager, Labeling
SOLGAR VITAMIN & HERB
500 Willow Tree Road
Leonida, New Jersey 07506 USA

Certified Mail – Return Receipt Requested
7000 0600 0024 1798 0299

October 30, 2001

Product Name	Structure Function Claim Or Statement	Dietary Ingredient (s)
Daily Harvest Cholesterol Support*	Cholesterol Support*	Guggulipids, Soy, Tocotrienols
Daily Harvest Energy Support*	Energy Support*	Coenzyme Q10
Daily Harvest Prostate Support*	Prostate Support*	Zinc, Soy
Daily Harvest Heart Health Formula*	Heart Health Formula*	Coenzyme Q10
Daily Harvest Eye Health*	Eye Health*	Lutein